

## **TITLE OF THE INVENTION**

### **PAD WITH A GEL LAYER HAVING COSMETIC OR THERAPEUTIC ACTIVITY**

## **FIELD OF THE INVENTION**

5           The present invention relates to a breathable pad, patch or the like, a surface of which is at least partially covered by a layer of semi-solid gel able to develop a decongestant, cosmetic or therapeutic action.

## **BACKGROUND OF THE INVENTION**

Physical or physiological states or alterations of the human  
10   organism very frequently determine conditions which must be counteracted using various remedies. For example, in the case of a simple cold, balsamic inhalations are used (in the form of nasal sprays, vapours, aerosols and the like) in order to free the airways of the nose; creams and ointments are used to counteract reddening of the lower part  
15   of the nose and the upper lip (due mainly to the rubbing of the handkerchief used to blow the nose); and cold water or ice packs are used to alleviate the sensation of heat.

Another example, in the case of ocular or periocular traumas or in the period immediately following eye surgery, the affected area is cooled  
20   with ice or water to prevent or reduce localized swelling (by developing a localized cryogenic action); active substances with anti-bacterial, anti-edema, decongestant and analgesic effect are applied to the affected area (to develop a therapeutic action); and the eye is covered with a pad, to impart an occlusive effect to the eye to retain on the eye the soothing,  
25   balsamic, aromatic and anti-bacterial vapours which have evolved from substances applied to the ocular region before the pad was rested onto it.

In these and in a large number of other cases it is therefore necessary to carry out a succession of separate operations which not only require time and attention but can often be carried out incorrectly.

The main object of the present invention is to form a flexible pad,  
5 one surface of which carries a layer of gel, and which can then be applied to the human skin, the gel being in each case able to exert a cooling effect on the skin to which it is applied and able at the same time to also exert a balsamic or soothing effect, while allowing the controlled release of drugs, aromas, essences or the like.

10 These objects are attained by a pad consisting of a flexible and porous support, on at least one surface of which a layer of gel is applied consisting of an intimate mixture comprising between 50% and 77% of water, between 6.5% and 44% of a dermatologically compatible polymer, between 0% and 10% of a substance of plant origin comprising essential  
15 oils and aromatic extracts; and between 0% and 10% of at least one dermatologically compatible component chosen from the group comprising soothing, skin repairing, cicatrising, anti-inflammatory, antiseptic and bactericidal substances, the percentages being by weight.

Preferably said gel comprises between 0.01% and 5.2% by weight  
20 of an alkaline or alkaline earth metal tetraborate and said support consists of a non- woven fabric made with fibres chosen from the group comprising viscose, polyester and polyethylene fibres, mixed polyester/viscose fibres, cotton and linen, said fabric support having a thickness between 15 and 200 microns, a density from 65 to 145 g/dm<sup>3</sup> and a weight between 15  
25 and 200 g/m<sup>2</sup>. Said support can also be coupled to a breathable or non-breathable plastic film, for example, of polythene, polypropylene,

polyurethane or polyester, said plastic supports having a thickness from 0.5 to 100 microns and a weight between 10 and 100 g/m<sup>2</sup>.

If required, said flexible porous support can be impregnated by the aforementioned substance of plant origin with a quantity up to 10% of the weight of the gel layer applied to the flexible support itself.

The gel can also contain between 0.001% and 5.2% by weight of a beneficial but non-essential compound chosen from the group consisting of solvents, wetting agents, preservatives, emulsifiers, stabilizers, solubilizers, surfactants and colorants.

Preferably, in the gel the water is present in a quantity of about 71%, the polymer of about 25%, substances of plant origin of about 5%, soothing, skin repairing, cicatrising, anti-inflammatory, antiseptic or bactericidal substances of about 5%, the percentages being by weight.

The preferred polymers are chosen from the group comprising polyvinyl alcohol, sodium alginate, calcium alginate, carboxymethylcellulose, sodium polyacrylate and polyvinylpyrrolidone.

The desired polymerisation can be achieved by treating the polymerizable components with  $\gamma$  rays or  $\beta$  rays (or UV rays), or by the addition of an alkaline metal or alkaline earth metal tetraborate.

The preferred essential oils and aromatic extracts are chosen from oils and extracts of silver fir, star anise, bitter orange, sweet orange, benzoin absolute, bergamot, cajeput, Roman chamomile, white camphor, cinnamon leaves, carrot seeds, citron fruits, cypress, citronella, eucalyptus globulus, extra sweet fennel, cloves, jasmine flowers, bourbon geranium, juniper berries, triple distilled juniper, incense absolute, iris, true lavender, cedarwood, guaiacan wood, rosewood, lemongrass, detergenated lemon,

lemon extra, litsea cubeba, marjoram, mandarin, Melissa, triple distilled  
peppermint, mimosa, myrrh, myrtle, neroli oil, niaouli, palmarosa,  
patchouli, petitgrain, Scots pine, Bulgarian rose, Riviera rose, rosemary,  
detergenated rosemary, clary sage, Mysore sandalwood, storax absolute,  
5 white thyme, vanilla, verbena, vetiver, ylang-ylang, ginger, menthol, tea  
tree.

Due to the warmth of the human skin to which the gel, spread onto  
the patch, is applied, the water begins to evaporate from the free surface  
of the gel, so causing cooling (cryogenic effect) of that part of the skin on  
10 which the gel is applied. Evaporation of the water causes molecules of  
aromatic substances (for example essential oils) which are possibly  
present in the gel to be drawn outwards, with consequent controlled  
release of aromatic and/or balsamic vapours which can be retained in  
contact with the skin for a long time since the gel is spread on a support,  
15 pad or patch applied to the skin itself. By osmotic effect, part of the water  
present in the gel flows into the epidermal interstices (with a consequent  
hydrating effect on the skin itself) favouring the penetration and absorption  
into the skin of any cosmetic or pharmaceutical substances possibly  
dispersed within the gel.

20 As the gel is spread onto a flexible porous support (pad or patch or  
the like), such porosity determines the rate (i.e. the duration in time) of  
water evaporation, thus enabling control of the rate or duration of transfer  
of cosmetic and pharmacological substances contained in the gel from the  
gel to the skin.

25 The possible application of a film made of plastic material, placed  
between the flexible support and the gel layer, can drastically reduce and

even completely eliminate evaporation of water from the skin to promote its hydration, giving a physiological environment with a high level of humidity.

### **DETAILED DESCRIPTION OF THE INVENTION**

5        Some non-limiting embodiments will now be described to further clarify the understanding of the nature, shape and structure and of the method of obtaining the pad.

#### **EXAMPLE 1**

Preparation of a decongestant nasal patch

10        30 kg of demineralised water, 0.120 kg of parabens (preserving agents) and 5.6 kg of polyvinyl alcohol are fed into a continuous mixer, heated to 70°C; mixing is continued until a uniform mass (Phase A) is obtained in which the polyvinyl alcohol is completely dissolved in the water, the mass then being cooled to ambient temperature.

15        Separately, 1.2 kg of demineralised water and 0.300 kg of sodium tetraborate are fed into a steel mixer heated to a temperature between 25° and 30°C, and stirred until dissolution is complete to give a uniform mass (Phase B).

20        0.180 kg of monopropylene glycol, 0.140 kg of 70% sorbitol, 5 kg of a mixture of extracts of Aloe Vera, Calendula and Hypericum perforatum, 3 kg of Eucalyptus, mint and white thyme essential oils and 20 kg of sodium alginate are added at ambient temperature (Phase C) to the same kneader (mixer) in which Phase A was prepared: the mass obtained in this manner is maintained under agitation for about 15-20 minutes while  
25        reversing the mixer rotation direction several times. The aforesaid Phase B is slowly added as a thin stream to this mass and mixing is continued for

about 20-30 minutes to thus form a gel in which the components of plant origin are intimately dispersed. The fluidity of the gel can be increased by increasing the amount of Phase A added to the mixer; vice-versa, the fluidity can be decreased by adding further quantities of Phase B to the mixer.

The gel thus obtained has cryogenic, cosmetic (balsamic) and cicatrising characteristics. A mass of said gel is placed in a doctor blade 2 (Figure 1) and is spread between two continuous bands 3 and 4 originating from two bobbins 5 and, respectively, 6.

The band 3 consists of a non-woven fabric of viscose fibres (65%) and polyester fibres (35%) forming a web (of the type known as "random") with a weight of  $50 \text{ g/m}^2$ , a thickness of 56 microns and a density of  $89 \text{ g/dm}^3$ .

The band 4 is formed from  $35 \text{ g/m}^2$  siliconized polyester

The two bands 3 and 4 converge towards two counter-rotating pressing rollers 7 and 8 positioned immediately beneath the doctor blade 2. A composite band 9 formed by the combination of the two bands 3 and 4 with a layer of the aforescribed gel therebetween leaves said rollers, the band 9 being rested on a moving belt which transports it to a machine of known type (not illustrated) which cuts and punches the band to give, for example, pads or patches 10 in the form shown in Figure 2 and which enables the patch itself (obviously after removal of the protective polyester film) to be applied under the nostrils so as to enable the balsamic action of the vapours which develop from the gel layer applied to the patch, the refreshing action due to the evaporation of water and the skin repairing action due to the active components in the gel.

In known manner the individual patches 10 can be inserted and preserved in airtight wrappers formed from several combined layers of different materials, for example PET/aluminium/polyethylene.

## EXAMPLE 2

### 5 Preparation of a decongestant nasal patch

28 kg of demineralised water, 0.120 kg of parabens (preservatives), 4.4 kg of polyvinyl alcohol and 0.5 kg of carboxymethylcellulose are fed into a mixer heated to 70°C to obtain a uniform mass (Phase A) which is cooled to ambient temperature and then poured into a kneader into which a  
10 Phase C, formed from 0.180 kg of monopropylene glycol, 2.0 kg of carboxymethyl betaglukan (having cicatrising action), 2.5 kg of eucalyptus, clove and black pepper essential oils and 18 kg of sodium alginate, is added while cold (over a period of about 15 to 20 minutes). The mixture is agitated for 15-20 minutes in both directions and then a Phase B,  
15 prepared separately by mixing 1.8 kg of demineralized water with 0.5 kg of sodium tetraborate in a steel vessel at a temperature of 20°-30°C until complete dissolution, is slowly added as a thin stream over a period of 20-30 minutes, to give a gel whose viscosity can be increased by increasing the amount of Phase B or decreased by increasing the amount of Phase  
20 A.

Proceeding as already described with reference to Figure 1, the gel is spread onto a band of non-woven fabric 3, formed from viscose fibres (50%) and polypropylene fibres (50%), constituting a "random" web structure with a weight of 54 g/m<sup>2</sup>, a thickness of 62 microns and a density  
25 of 87 g/dm<sup>3</sup>.

The protective band 4 consists of a 75 g/m<sup>2</sup> siliconized polyester sheet.

The composite band 9 leaving the rollers 7, 8 is transported to a machine (not shown) where it is cut and punched taking the form, for example, of the patch 10 shown in Figure 2.

As with the case described in Example 1, the patch thus obtained ensures a refreshing, balsamic action (due to the vapours which evolve from the gel) and skin repairing action (due mainly to carboxymethyl betaglucan).

### 10      EXAMPLE 3

Preparation of a decongestant nasal patch in which the balsamic action is produced by essential oils subsequently imbibed into the fabric

28 kg of demineralised water, 0.120 kg of parabens (preservatives), 4.4 kg of polyvinyl alcohol and 0.5 kg of carboxymethylcellulose are fed into a

15      mixer heated to 70°C to obtain a uniform mass (Phase A) which is cooled to ambient temperature and then poured into a kneader into which a Phase C formed from 0.180 kg of monopropylene glycol, 2.0 kg of carboxymethyl betaglucan (having cicatrising action), and 18 kg of sodium alginate is added cold (over a period of about 15-20 minutes). The

20      mixture is agitated for 15-20 minutes in both directions and then a Phase B, prepared separately by mixing 1.8 kg of demineralized water with 0.5 kg of sodium tetraborate in a steel vessel at a temperature of 20°-30°C until complete dissolution, is slowly added as a thin stream over a period of 20-30 minutes, to give a gel whose viscosity can be increased by increasing

25      the amount of Phase B or decreased by increasing the amount of Phase A.



Proceeding as already described with reference to Figure 1, the gel is spread onto a band of non-woven fabric coupled to a 35 microns microperforated polythene film 3, formed from viscose fibres (50%) and polypropylene fibres (50%), constituting a "random" web structure with a weight of 150 g/m<sup>2</sup>, a thickness of 200 microns and a density of 87 g/dm<sup>3</sup>.

The protective band 4 consists of a 75 g/m<sup>2</sup> siliconized polyester sheet.

The composite band 9 leaving the rollers 7, 8 is transported to a machine (not shown) where it is cut and punched, for example, to assume the form of the patch 10 of Figure 2 and imbibed using two nozzles that spray a mixture composed of Eucalyptus, clove and black pepper essential oils onto the fabric, in a quantity of 200 milligrams per patch.

As with the case described in Example 1, the patch thus obtained ensures a refreshing, balsamic action due to the vapours which are released from the non-woven fabric imbibed with oils, and a skin repairing action (due mainly to carboxymethyl betaglucan). In this instance, said patch ensures there is no contact between essential oils and the skin in cases where such a circumstance is necessary due to irritation problems. Moreover, the coupled plastic film does not allow essential oils to migrate towards the gel.

#### EXAMPLE 4

##### Preparation of a decongestant nasal patch

A liquid Phase A comprising 18.01 kg of water, 1.05 kg of isopropyl myristate, 0.7 kg of glycerol, 0.18 kg of titanium dioxide, 8.75 kg of carboxymethylcellulose, 1.75 kg of kaolin, 0.7 kg of tartaric acid, 0.7 kg of polysorbate 80, 1.05 kg of sorbitan sesquioleate, 0.7 kg of sodium

polyacrylate, 0.35 kg of dihydroxyaluminium aminoacetate, 0.35 kg of propyl parahydroxybenzoate, 0.7 kg of 1,3-butylene glycol and 0.02 kg of phenol methylpropyl paraben is prepared in a mixer heated to 70°C, cooled to ambient temperature and mixing continued for 30 minutes in a kneader into which 0.7 kg of mint essence, 0.35 kg of camphor, 0.35 kg of menthol, 0.35 kg of white thyme and 0.35 kg of liquorice are added and mixing continued for 20 minutes.

Then, again at ambient temperature, 0.35 kg of Hypericum perforatum, 0.35 kg of Calendula and 0.35 kg of Bisabolol are added, while continuing to mix for 20 minutes.

A gel is hence obtained which, in the manner described with reference to Figure 1, is spread (by means of the doctor blade 2) onto a 35 g/m<sup>2</sup> siliconized polyester protective band. Fixing a distance of 50 microns between the opposing surfaces of the rollers 7 and 8, after leaving said rollers 7, 8 the polyester band with the gel spread thereon is passed through a 1.20 Mev power beta ray chamber for about 30 seconds to promote the polymerisation of the polymerizable components of the gel. A viscose (50%) and polyester (50%) non-woven fabric with a "random" web structure with a weight of 54 g/m<sup>2</sup>, a thickness of 62 microns and a density of 87g/dm<sup>3</sup> is then coupled (by means of counter-rotating rollers similar to the rollers 7,8) to that face of the polyester band on which the gel layer is present.

The composite band obtained in this manner is transported by a moving belt to a machine where the band is cut and punched into patches 10 with the profile shown in Figure 2, which are then enclosed, preserved

and sealed in wrappers of known type (formed from layers of PET/aluminium/PEL).

The patch described can be applied on the upper lip and under the nostrils, to enable the already stated refreshing balsamic action of the vapours, and the skin repairing action.

#### EXAMPLE 5

##### Preparation of a pad for ocular gel

A liquid Phase A consisting of 32 kg of demineralised water, 0.120 kg of parabens (preserving agents), 4.8 kg of polyvinyl alcohol and 0.150 kg of chlorhexidine is prepared in a mixer heated to 70°C; the mass obtained is cooled and poured into a kneader into which 0.180 kg of monopropylene glycol, 0.140 kg of 70% sorbitol, 0.5 kg of betaglycyrrhetic acid, 0.8 kg of pineapple extract, 0.8 kg of Echinacea extract and 18 kg of sodium alginate are added, stirring in both directions for 15-20 minutes.

A solution of sodium tetraborate (0.200 kg) and demineralised water (0.8 kg) is prepared separately in a steel mixer heated to 25-30°C, to give a Phase B which is slowly added as a thin stream to the aforesaid kneader in which the mass is maintained in movement for a period of 20-30 minutes, giving rise to the formation of a gel whose fluidity can be increased by increasing the quantity of the Phase B, or decreased by increasing the quantity of the Phase A.

Using the system outlined in Figure 1, said gel is spread, by means of a doctor blade 2 and two counter-rotating blades 7, 8, between a band of 50 g/m<sup>2</sup> pure viscose fabric and a protective band of 70 g/m<sup>2</sup> siliconized PET and is then cut, punched and wrapped.

In this manner pads 11 are obtained having the elliptical shape shown in plan view in Figure 3, a plurality of perforations 12 being provided along the periphery of the pad itself, which at its centre is also provided with a long longitudinal incision 13.

5        The shape of the pad allows it to be applied over an eye so as to lightly compress the eyelids, allowing any discharge to drain from the perforations 12 and incision 13.

      If necessary, a conventional plaster can be placed over the pad to retain the pad firmly on the eye.

10        EXAMPLE 6

      Preparation of a pad for ocular gel

33 kg of demineralised water, 0.150 kg of parabens (antioxidants and preservatives), 5.3 kg of polyvinyl alcohol, and 0.8 kg of carboxymethylcellulose are fed into a mixer heated to 70°C and stirred  
15    until dissolution is complete. The mixture is cooled and poured into a kneader into which 0.140 kg of 70% sorbitol, 0.8 kg of betaglycyrrhetic acid, 0.3 kg of pineapple extract, 0.3 kg of Echinacea extract and 12 kg of sodium alginate are added and is mixed in both directions at ambient temperature for about 20-30 minutes, after which a Phase B, prepared  
20    separately by mixing 1.2 kg of demineralised water with 0.150 kg of sodium tetraborate at 25-30°C in a steel vessel until dissolution is complete, is slowly added as a thin stream. A gel is obtained whose fluidity can be increased by increasing the quantity of Phase A or decreased by increasing the quantity of Phase B.

25        The gel can be spread in the manner already described onto a 50 g/m<sup>2</sup> non-woven fabric pad of pure viscose protected by a 70 g/m<sup>2</sup> sheet of

siliconized PET, which can be then punched to assume the form of Figure 3 and then be applied over an eye to develop a localized cooling, anti-edemic and healing effect, in exactly the same manner as described in Example 4.

#### 5        EXAMPLE 7

Preparation of a pad for ocular gel

A liquid Phase A formed of

	water	17.85
	gelatin	2.8
10	polyvinylpyrrolidone	4.55
	sorbitol 70	0.88
	Kaolin	0.88
	titanium dioxide	0.18
	monopropylene glycol	1.05
15	methylparahydroxybenzoate	0.35
	propylparahydroxybenzoate	0.35
	disodium edetate	0.18
	tartaric acid	0.18
	dihydroxyaluminium aminoacetate	0.18
20	carboxymethylcellulose	4.90
	sodium polyacrylate	0.70

the values being expressed in kg, is prepared in a mixer heated to 70°C.

The homogenous mass thus obtained is cooled to ambient temperature, while continuing to mix for 30 minutes, then 0.05 kg of mint  
 25 and 0.10 kg of liquorice are added and mixed for a further 20 minutes and finally 0.7 kg of glycolic extract of pineapple, 0.7 kg of glycolic extract of

Echinacea and 0.35 kg of betaglycyrrhetic acid are added, continuing to mix for a further 20 minutes.

In this manner a gel is obtained which is spread (by means of a doctor blade and two counter-rotating rollers spaced 50 microns apart) onto a 35 g/m<sup>2</sup> band of siliconized polyester. The polyester band with the gel spread thereon is passed through a chamber where it is subjected to radiation by UVA rays of about 220 nanometers for about 30 seconds to promote polymerisation, and is then coupled to a viscose (50%) and polyester (50%) non-woven fabric band, of "random" web structure, with 54 g/m<sup>2</sup> weight, 62 microns thickness and 87 g/dm<sup>3</sup> density.

By punching, pads are obtained similar to that shown in Figure 3, which can be applied over the eyes to provide an effective refreshing balsamic action by the vapours and a skin repairing action.